EME ITALY

ULTRASONIC 1300-1500

Manuale d'uso | User's manual | Mode d'emploi
Gebrauchsanleitungen | Manual de instrucciones
Руководство по эксплуатации

Italian manufacturer of physiotherapy equipment since 1983

CE 0476

INDEX

INFORMATION ON THIS MANUAL

This manual is addressed to:

- user of the machine;

- owner;

- responsible;

- people in charge of moving;

- installers;

- users;

- people in charge of maintenance.

This document provides valuable information regarding the installation, set up and use of ULTRASONIC-series equipment.

It is a useful and essential reference guide for the user: read the contents of the manual carefully before installing the equipment and keep it on hand at all times for future reference.

It is of vital importance that you strictly adhere to the recommendations contained within the manual in order to avoid malfunction, which may cause damage to the equipment and consequent annulment of the validity of the warranty.

Furthermore, in order to obtain the highly efficient technical service available from the manufacturer, it is essential that any handling of the equipment be in accordance with the instructions provided.

The limits of this manual are:

- the user manual cannot replace proper experience;

- the user manual, for particularly difficult operations, can only be a reminder of the main operations.

The manual is to be considered part of the equipment and must be preserved for future reference until the decommissioning of equipment. The operating instructions must be available for consultation in the vicinity of the machine and properly stored.

This manual reflects the state of the art at the time of sale and cannot be considered inadequate because later updated based on new information. The manufacturer has the right to update products and manuals without necessarily updating preceding products or manuals, unless these have implications for the safety of the device.

The company will not assume any responsibility for any major cases:

- improper use of the machine;

- use against to specific national regulations;

- incorrect installation;

- defects in power;

- serious shortcomings in maintenance;

- changes and unauthorized interventions;

- use of parts or materials not specific to the model;

- total or partial non-observance of the instructions;

- exceptional events.

If you would like any further information, please get directly in touch with the company EME srl, to stay up to date on the best ways to use these machines and to receive the necessary assistance.

WRITING CONVENTIONS

Certain sections of the manual have been underlined in order to highlight their importance.

NOTE

These contain important information and useful tips for operating the equipment

CAUTIONS

The CAUTION message appears before operations, which, if not correctly performed, may cause damage to the machine and/or its accessories.

! WARNING !

This signals operations or situations, which, if unknown to the operator, or incorrectly carried out, may harm the operator.

WARRANTY

EME srl guarantees the quality of its products for a period of 24 months from the date of purchase, when information contained in this manual regarding installation, use and maintenance is strictly adhered to and the warranty coupon is returned within 15 days of purchase.

The guarantee covers the replacement of faulty parts.

The warranty does not however, include the replacement of the equipment.

The warranty does not cover any malfunction or damage caused by:

- incorrect connection and installation;
- incorrect use due to non-compliance with instructions contained in this manual;
- use of the machine in environmental conditions which do not conform with those specified for the product;
- improper or inadequate maintenance;
- unauthorized opening of the outer casing;
- tampering or unauthorized modifications;
- use of non-original accessories.

EME srl registered offices provide the warranty.

Should you need to return the goods then please note the packing instructions as follows. Enclose a copy of the purchasing receipt.

You should insure the postal package.

Before sending the machine back for suspected malfunction, we recommend that first you carefully consult sections regarding MAINTENANCE and TROUBLESHOOTING of the manual, as a large part of the problems and faults are usually due to inadequate maintenance or small technical problems which can often be easily solved by the user himself.

A simple call to EME srl technical department may prove to be the solution to the problem .

When re-packing the equipment for return to the manufacturer, proceed as follows:

1. unplug the machine and any connections, devices, applicators etc;

2. carefully clean and disinfect all parts of the machine and accessories which have been in contact with patients.

Any equipment which the technical department does not consider hygienic (Italian law T.U.S. 81/2008 on safety in the workplace) will not be accepted;

3. disassemble accessories and any mechanical supports;

4. use original box and packing materials;

5. enclose detailed information regarding the nature of the problem in order to facilitate the technical department's intervention and save time on repair.

NOTES

PRELIMINARY NOTES

- The installation of the device does not require any special care, is therefore simple and immediate.

USE

- Each time you click the START button or the STOP button the machine will emit a long confirmation beep.
- Each time you select the SMART-CARD will take a few seconds to allow the machine to recognize and load the card: meanwhile it shows the message PLEASE WAIT.
- The selection of the SMART-CARD is possible only if previously inserted into the slot.
- To prevent erasure or formatting of SMART CARD, confirmation is required.
- To navigate the software it is necessary to use the encoder knob that can: rotate (both clockwise and anticlockwise) by moving the selection of an option, or confirm the selection by pressing the knob itself.
- The keys shown on the display are touch.

MAINTENANCE

- For an optimal use of the device and to guarantee its maximum performance, it is recommended to perform maintenance at the correct time and suggested ways.

CAUTIONS

PRELIMINARY NOTES

- The customer is liable for all damage caused by inadequate packaging of the material. Keep the original packaging of the unit: it will be needed if the unit is returned to the company.
- Do not use the equipment in places where it might get wet.
- Before operating the machine carefully check the correctness of the connections according to the instructions.
- To avoid the risk of electric shock, this device must only be connected to power supply networks with protective earth.
- Do not use accessories other than the ones provided: they might damage the unit, causing the warranty to become void. In case you have any problems or difficulties with installation, contact EME srl technical support.

- If using the same extension for the unit and other units, make sure that the total current being absorbed by the connected units, does not exceed the max current allowed for that type of cable and that, however, it does not exceed 15 A.
- The therapeutic suggestions are stored in the permanent memory of the machine. These protocols can be edited but not possible to save any changes.
- The protocols of therapeutic suggestion preloaded on the machine cannot be deleted.
- It is not possible to define a number of sessions suggested to evaluate the effectiveness of the treatment, since they are related to the power delivered to the patient undergoing treatment. E 'task of the physician to decide the number of therapy sessions which subject the patient according to the specific requirements of the case, in order to ensure to the patient himself the execution of an effective treatment in time and place in conditions of absolute safety.
- Always control sometimes the integrity of the cable and of the probe/applicator connector: they must not be damaged or worn.
- It's a class A machine in terms of emission. The EM device is suitable to be used in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
- Do not use the machine near HF SURGERY DEVICES and rooms with an RF shield of an EM system for magnetic resonance, in which the intensity of the EM DISORDERS is high.
- No modification of this device is allowed.
- The use of accessories, transducers and cables, other than those specified or supplied by EME srl, could lead to higher electromagnetic emissions or a decrease in the level of electromagnetic immunity of the appliance, with consequent incorrect operation.

USE

- On request we can provide the user manual in electronic form.
- Because of security reasons, the only specific software must be loaded into each machine. In case of exchange of software, the machine may immediately stop all its functions, requiring the intervention of EME srl technical assistance.
- La The Smart Card has to be introduced keeping the golden chip facing up.
- A new ***Smart- Card*** has to be initialized using **FORMATTING** before being used.
- In case of selection of this type of memory if the card is introduced in wrong way or is not formatted or results not correct, a warning window will appear with the information about the error. Close the window clicking OK to continue.
- SMART-CARD option is visible (and therefore selectable) only if the smart-card is properly inserted in its slot. In case of lacked insertion of the Smart-card in its slot or Improper insertion, the option button SMART CARD is not visible, for which a possible selection does not involve any action.
- The selection of programs to be loaded takes place by default in the user memory, that in cases of non-presence of the Smart-card (due to its lack or to an improper insertion in its slot) is the only support of available memory to load customized programs.
- Never swap ultrasound probes of the same or different devices, because each probe emits at specific frequencies that are different from any other probe. These frequency are previously set in the channel where the probe shall be used..
- The devices for ultrasound therapy automatically recognise the probe plugged to the output connector. For the probes supplied with the device, this operation **is not executed** because the frequencies specific of the supplied probe are set in the factory, during the testing phase of the device.
- In order to ensure successful treatment, it is very important that the transmitting head adheres perfectly to the treatment area, in order to avoid the temporary or permanent appearance of air bubbles as much as possible. Bubbles would reflect part of the radiated Energy and cause overheating of the skin in the areas of poor contact.
- **When treating in the CONTINUOUS modality, the power must be set at a lower level in order to avoid the painful feeling due to the administration of energy concentrated in a single spot.** The negative phenomena, connected to an eccessive thermal effect, can be eliminated using a pulsed emission treatment, that delivers adequate peak power. without provoking overheating in the treated area.
- The appliance or the system must not be used near other equipment and, if it is necessary to use it near other equipment, the medical electrical equipment must be observed to check normal operation in the configuration in which it is used.
- If the electro-medical device, interacting with another device, causes or receives detectable interferences, the user is invited to limit the interference by adopting one or more of the following measures:
    - Reorient or reposition the receiving device;
    - Increase the distance between the devices;
    - Connect the equipment to a scale of a circuit different from or to devices that cause interference;
    - Contact the manufacturer or local technician for assistance.
- Portable and mobile radiocomunication devices can affect the operation of the device.
- transportable RF communication equipment (including peripherals such as antenna cables and external antennas) should be used at a distance not less than 30 cm (12 inches) from any part of the device, including the specified cables. Otherwise, the performance of this device may be degraded.

MAINTENANCE

- Use the probes/applicators with care: any misuse may affect their performance and features.
- Under no circumstances technicians not authorized by EME srl are allowed to open and/or disassemble the probe/applicator: such tampering, besides damaging its characteristics, immediately invalidate the right to warranty.
- The equipment should never be disassembled for cleaning or inspection purposes: the units does not have to be cleaned internally, and if for some reason the unit must be opened, it should only be done by specialized technicians authorized by EME srl.
- Do not use thinners, detergents, acid solutions, aggressive solutions or flammable liquids to clean the external parts of the unit and accessories. Using these substances, or misusing the accessories, will cause the immediate voiding of all warranty rights, as well as irreparably damaging the unit and the accessories.
- For optimal use of the apparatus and to ensure its optimum performances it is recommended to perform properly within the time and in the manner recommended maintenance actions.
- For a correct replacement of the installed fuses, observe the following indications:

1. disconnect the power supply and open the fuse box using a screwdriver, makingsure you insert the screwdriver in the slot on the fuse box and levering up outwards;
2. insert a screwdriver into the two side holes for fuse expulsion
3. remove the old fuses
4. insert a new fuse at a time by using a slight pressure to the left, with a finger
5. push the box back to fit into the slot.

- It is recommended to perform periodic maintenance every two years, in order to check:
  - the intensity of any leakage currents;
  - the continuity and thus the integrity, of the ground conductor;
  - the correctness of the value of insulation resistance;

  in order to ensure the electrical safety of the device, ensure that it is operating in a safe guaranteed. For this kind of intervention you should contact a qualified service technician or alternatively EME srl or one of its authorized service centers.

WORKING PROBLEMS

- Only technicians authorized by the manufacturer may access the interior of the unit.
- You should contact EME srl or its authorized service centers for any repair work or further information.

! ATTENTION !

PRELIMINARY NOTES

- The perfect functionality of the device is guaranteed in accordance with the rules of installation and of use included, only with original accessories and spare parts.
- If there are problems or installation difficulties, please contact the EME srl technical assistance department.
- The correct position while moving the machine without trolley: the apparatus has to be moved exclusively by gripping it with both hands on the curved profiles of the lid.
- Before connecting the cable to the mains plug, check that the equipment wasn't damaged during transport. Ensure that the power supply specifications on the mains socket correspond with the information on the label attached to the back of the unit.
- The electric current that powers the unit is VERY DANGEROUS. Before connecting or disconnecting the power cable from the connecter on the unit, make sure it is plugged out from the mains socket.
- The power cable has an earthed plug for safety reasons.
- Only use with a mains socket suitable for use with earthed systems
- **The equipment should only be connected to electrical systems that fully comply with regulations.**
- If you are using extension cables, verify that there is a ground cable and that it is intact.
- Connect the equipment directly to the wall socket without using extensions. Failure to comply with these warnings may result in dangerous electrical discharges that could cause injury operators and compromise the functioning of the unit.
- The manufacturer is held responsible for the fundamental safety, reliability and performance of the device only if:
  - The electrical system of the premises complies with the appropriate regulations;
  - The device is used in accordance with the instructions for use.

USE

- In order to ensure the functioning of the machine in conditions of absolute safety for the patient, the operator must pay attention to the necessity of a periodic maintenance (every 2 years) of the equipment. EME srl authorized personnel should carry out such operations.
- It absolutely forbidden the use of the device in the presence of a flammable anesthetic mixture and oxygen-rich environments. In case of non-compliance with this indication, EME srl will not be responsible for any accidents.
- It is absolutely forbidden to cover the ventilation slots: such an action may not allow the machine to work in safe conditions. In case of non-compliance with this indication, EME srl will not be responsible for any accidents.
- It's important to pay the attention of the operator to the necessity to verify the correctness of the electric installation of device before activating the supply switch.
- It is advisable to suspend the therapeutic treatment if it were to appear some disturbances during its emission.
- It's strongly advised not to hold the device on in state of start without using the probe, it could overheat.
- If the button OK is pressed to confirm the software updating before having connected the USB-port to the source containing the software updating, the device goes out from the main program and enters in the updating routine waiting for the USB connection. A screen indicates the missed connection. If the support to connect to carry out the updating is not available, it is necessary to switch off the device and turn it on again through the general switch to restart the device with the available software.
- In order for the probe to be perfectly recognized by the device, make sure you connect/disconnect it while there is no treatment emission going on.
- If you administer ultrasound therapy near a shortwave device or microwave device the emission of ultrasound can turn instable.

MAINTENANCE

- For safety reasons before carrying out any maintenance or cleaning the unit, **YOU MUST** turn off the equipment with the power switch at the back and unplug the socket connected to the mains.
- Before every treatment, it is recommended to clean with caution all of the accessories and the parts of the equipment that have been to contact with the patient.
- The operator must pay attention to the necessity of a periodic maintenance (every 2 years) of the probes/applicators. EME srl authorized personnel should carry out such operations.
- The cleaning and disinfection must be done systematically before the therapeutic treatment which subject the patient.
- Do not use thinners, detergents, acid solutions, harsh solutions or flammable liquids to clean the outside of the unit and its accessories. The use of these substances, with the improper use of accessories, irreparably damages the equipment and the warranty will lapse.
- Always control sometimes the integrity of the cable and of the probe/applicator connector: they must not be damaged or worn.
- Before delivering the treatment, check the integrity of the emitting head by carefully checking the absence of cracks that could allow the entry of conductive fluids.

- It is advised that personnel with technical preparation substitute the fuses, to perform the operation in safety conditions.
- Do not open the device: inside there are high voltages that may be hazardous.
- Only personnel authorized by the manufacturer may access the internal components. For repairs and further information please contact EME srl or its authorized service centers.
- As the emission of ultrasound in the CONTINUOUS operating mode is continuous, **the operator is responsible for checking** that the emitting probe head is adhering well to the treatment area in all its parts, in order to avoid that air bubbles form or stay in area, thus causing the partial reflection of emitted energy and consequently causing an overheating effect.

WORKING PROBLEMS

- Do NOT OPEN the unity, as HIGH VOLTAGE ELECTRICITY is present and may prove VERY DANGEROUS.

INTRODUCTION TO THE TECNOLOGY

THE PHYSICS OF ULTRASOUND

Ultrasounds are elevated frequency sound waves (of more than 16,000 cycles/sec), not perceptible to the human ear, that exist within nature (for example in the cries of bats, diapasons, etc.). Such waves can also be artificially produced in numerous different ways, although in the medical field this is done by means of the inverse "Curie" effect.

They are propagated under the form of longitudinal compression waves in the presence of a means capable of being compressed; the movement of the particles in the compressed means takes place parallely to the wave or propagation, meaning that the sound cannot be transmitted through empty space.

The fundamental characteristics of sound waves are:

- the length of the wave,

- the speed of propagation,

- the frequency measured in cycles (the cycle or period measures the number of sound oscillations in 1 second).

In the medical field ultrasonic vibrations are obtained through maniples that take advantage of the piezoelectricity and the reciprocal piezoelectric effect of quartz. This effect lies in the characteristic property of quartz crystals that produce electrical charges when subject to depression and traction forces.

The simplest piezoelectric generator consists of a plate made of quartz (or other piezoelectric material) onto whose surfaces an alternative potential difference, with a frequency able to take the crystal into resonance, is applied.

Ultrasonic vibrations propagate themselves in different ways according to the means within which they travel, in relation to the facility and speed with which the means itself can be deformed.

This depends on a physical characteristic, known as the **acoustic impedance**, of each material. The greater the difference of acoustic impedance between two materials, the greater the quantity of rays that will be reflected, that is to say, not transmitted.

The sound waves travel quicker in materials with greater specific acoustic impedance; therefore, they propagate easily in metals, quite easily in water and yet with great difficulty in air where acoustic impedance is very low.

In the human body ultrasound beams are diffused in all directions thanks to small reflectors, such as, for example, erythrocytes, that behave like elastic points of diffusion and vibrate at the incident sound frequency diffusing energy in all directions.

There is, however, a certain difference between propagation in water and that through human tissues, to the disadvantage of the latter. Therefore, in order for ultrasounds to have the same biological effect in water treatments it is necessary to decrease the frequency and length of application, with the biological effect of the ultrasounds being slightly quicker.

It is, however, obvious that applications in water should only be carried out on suitable parts of the body (such as hands and feet) as it is not easy to carry out ultrasound treatment on a knee in water!

Substance	Propagation speed cm/sec	Specific acoustic impedance*** gr/cm^2/sec.
Air	331	43
Carbon dioxide	260	51,5
Hydrogen	1260	11,5
Distilled water 19°	1461	146.100
Ice	2100	190.000
Iron	5000	3.900.000
Glass	5400	1.350.000

Table1: Values of propagation and specific acoustic impedance of ultrasounds in given substances.

*** the specific acoustic impedance derives from the relationship between the density of the fluid times its propagation speed (I = D x V) and is specific to individual substances.

Ultrasound intensity is expressed in Watt/cm^2, it refers to the average intensity of the field, and is got by measuring the total output of the treatment (Watts) from the handpiece probe and dividing by the radiating surface area of the applicator.

$$I = Wu / s$$

Where: Wu = output in watts, s= applicator surface.

Ultrasound emitting units used in physiotherapy are manufactured on the above referred to principles and feature:

- an alternate current generator with a frequency of between 500 KHz and 3 MHz; this should be aligned with the quartz frequency to ensure maximum power dissipation. More advanced units, such as those in our Ultrasonic range, operate in both continuous and pulsated (100-120 Hz pulsation frequency) modes; some units have, however, been designed to work in pulsated mode at a frequency of 16-48 Hz. This frequency is important as a number of studies seem to suggest that the kick start system, which plays an important role in the regeneration of bone tissue, is activated and stimulated by ultrasounds at a frequency of 16Hz and multiples of the same;

- a high tension shielded cable that connects the generator to the head and which supplies it with the high frequency produced by the generator;

- an emitting head housing the quartz (nowadays replaced by various materials such as barium titanite) onto whose surfaces an alternative potential difference with a frequency able to take the crystal into resonance is applied. The size of the emitting head can vary between 1cm2 and 10 cm2. The irradiation proprieties of each head therefore depend upon its diameter and the length of the wave, with the sound irradiation produced by the transducer penetrating the tissues in a conical form. In order to have a therapeutic effect on in-depth human tissues, the emitting head must be able to produce an average intensity of 3watt/cm2. A head with a radiating surface of 10 cm2 should have a maximum total output of between 30 watts.The heads of our ultrasound units feature a non-contact luminous indicator that informs the user as to incorrect contact between tissues and the emitting head, and these heads are self-calibrating meaning that they do not need to be reset at any time.

The units ULTRASONIC-series, supplying both continuous and pulsated ultrasounds, have a duty cycle adjustment feature that significantly decreases the diathermic effect as heat is dispersed in the interval between one impulse and the next.

In addition, pulsated emissions offer the technical advantage of reducing the probability of transducer overheating and allow for the use of greater intensities.

PHYSIOLOGY AND EFFECTS ON HUMAN TISSUES

The application of ultrasounds on human tissues translates into a high frequency cellular and intercellular massage action. The tissues irradiated with ultrasounds start, in turn, to vibrate resulting in the use of energy and production of heat.

The biological effects of ultrasounds, that is to say, the mechanical and diathermic effects, can be seen in these manifestations.

The MECHANICAL effect develops by means of rhythmic tissue compression and decompression. The particles of a tissue subjected to the vibrating beam are all alternately excited at the same level of speed and acceleration.

The ultrasonic radiation penetrating into the tissues undergoes a progressive weakening in terms of intensity. In the point of passage from the transducer to the skin there is the first limit layer effect, that is to say, the first phenomenon of energy dispersion and re-absorption. The effects of the limit layer become more noticeable at greater depths, particularly at the point of passage between the soft tissues and bone, where the difference in resistance between the two means in contact causes particularly elevated reflection.

The bone tissue, nevertheless, does not completely reflect the ultrasonic beam but rather absorbs a fraction of it, while a rather significant fraction is absorbed by the periosteum which notably overheats with consequential painful sensations that may be provoked by excessively long or high-powered application.

The DIATHERMIC mechanism with assumable biological effects starts to become possible at energies of 1 watt/cm2. As the sound propagates through the tissues it is absorbed and converted into heat.

The distribution of the temperature produced by ultrasounds in the tissues is unique in terms of forms of deep heating: in fact, it causes a relatively small increase in temperature on tissue surfaces and has a greater probability of penetrating into the musculature and soft tissues compared to the diathermy produced with microwaves or short waves.

The temperature of articulations covered with heavy masses of soft tissue, such as, for example, the hip, can be increased to therapeutic levels and levels of tolerance that have no detrimental effects on other tissues.

Endotissular hyperthermia manifests itself quite rapidly and is followed by the establishment of a state of thermic balance determined by the dispersion provoked by the blood flow.

Further effects, in addition to these two main effects, are chemical and neural effects.

The CHEMICAL effect seems to be linked to a characteristic phenomenon induced by ultrasounds, known as “cavitation”, that can be seen when the small gaseous bubbles in the liquid components of tissues increase in size translating into oxidization, polymerisation and macro-molecule destruction processes, etc.

Therefore, ultrasounds, at non-detrimental doses, increase exchange favouring diffusion processes and humoral exchanges through the cellular walls.

The NEURAL effect is linked to the influence of ultrasounds on the neuro-vegetative system. Different tissues absorb ultrasounds in different ways: soft tissues at a frequency of 1 MHz attenuate radiation of 1 db/cm, that is to say that in between 15 and 30 mm of tissue only half the energy will be absorbed and the intensity will be reduced to approximately 1/2 of the initial value.

The penetration depth of ultrasonic energy in the muscle is particularly marked: at a depth of approximately 3 cm the intensity is still approximately half that measured at the muscle surface.

A number of scientific experiments have shown how the absorption of ultrasound energy greatly increases the extensibility of connective tissues leading to significant applications in the treatment of scar tissue, superficial articular capsules and cases of tendinitis.

Applications techniques

Correct ultrasound application requires perfect contact between the emitting head and the tissue in so far as the interposition of layers of air reduces the penetration capacity of the radiation.

Sometimes the area to be treated has an uneven surface making correct direct contact application impossible, although this can be remedied by placing a synthetic rubber pad (filled with oil, anhydrous petrol, degassed water or conductive gel) slightly larger in size than the emitting head, between the transducer and the skin.

A range of different application methods can be used.

The DIRECT and MOBILE CONTACT treatment is the most widely used form of treatment. A greasy cream, Vaseline or conductive gel is spread over the area to be treated in order to allow for better skin ultrasonic wave transmission. The emitter head is directed using circular or up and down movements.

In the DIRECT and FIXED CONTACT treatment, the head can also be held in a fixed position on the part to be treated, spread with a transmitting substance, for the whole length of the session, although in this case it is necessary to lower the power emitted in order to avoid creating patient discomfort (pain is caused by the excessive absorption of ultrasonic energy, for example, in articular and periosteum treatments) or to carry out the treatment using the pulsated mode.

The INDIRECT SUBAQUEOUS CONTACT treatment involves immerging the body part to be treated in a water bath; the emitter head is immersed in the water a short distance from the part to be treated and is moved parallel to the latter.
The emitting maniples of ULTRASONIC-series unit are specially designed for this type of treatment. The part to be treated is immersed in a recipient (better in metal because it is more reflective) containing water together with the emitting head which is positioned at a maximum distance of 2-3 cm from the body surface in order to avoid an excessive dispersion of the ultrasonic beam with a related decrease in therapeutic effects. The ultrasonic vibration is transmitted in a relatively uniform manner in the liquid and homogeneously enters the immersed segment of the body. This method is recommended when it is necessary to treat irregularly-shaped parts of the body (elbows, malleoli, hands, feet, etc), ulcerated areas or hyperesthetic skin zones that cannot withstand pressure. It is a useful method to employ when the surfaces to be treated are particularly small or irregular, or when the area is too painful to permit direct contact.

In the COMBINED treatment (bipolar technique) the specially designed unit, through its metallic head surfaces, emits ultrasounds and impulsive low and medium frequency antalgic-effect currents, or infrared radiation laser energy, contemporaneously.

The SONOPHORESIS involves the localised administration of pharmacologically active substances applied, in place of the gel, in the form of products designed for local use.

IN GENERAL

EME srl has recently developed a complete series of apparatus, accessories and equipment, designed and manufactured according to the highest standards of quality, making use of the latest technology and fully adhering to current directives and norms.

Particular attention has been paid to the design, easy operation, function and safety of the equipment and the final result is this modern, compact unit, which offers an extremely logical operative sequence supported by a clearly legible display .

A wide range of therapeutic applications, and guaranteed patient and therapist safety ensure that equipment is of the highest quality.

The equipment were planned and built in manner that their use, if it happens at the conditions indicated, doesn't compromise the health and safety of the patients, of the users and of third, taking into consideration the benefit to the patient.

Such equipment are not bound to diagnosis, prevention, monitoring, compensation of injury or handicap, substitution or modification of the anatomy, control of the conception, support/vital support of functions but allow to treat special pathologies and to reduce the illness.

A special intervention is not required in the event of failure of the medical device, but just a normal maintenance/repair.

INTENDED USE

ULTRASONIC-series is an electro-medical device that delivers ultrasound treatments, with the help of probes/applicators for the provision of treatment.

The use of these equipment is reserved for operators, such as physiatrists, physiotherapists and pain therapists, that, by their training, provide assurance of proper use and safe for the patient.

In fact, the operator must be appropriately qualified and he carefully studied the contents of the user manual in order to use the device; or, he must operate under the supervision of a health professional adequately qualified to use the machine, able to understand the benefits and the limits of therapy and to work in conditions of safety for the person undergoing treatment.

Such equipment can be used in hospital environment outpatient, nevertheless, it is important to know that the user follow the medical instructions to use the equipment or that he follow the indications present in the user's manual.

ULTRASONIC-series is a machine produced according to the Directive MED 93/42/EEC concerning medical devices.

INDICATIONS

ULTRASONIC-series is particularly indicated for the treatment of the following diseases:

- Algia articolaz. temporo-mandibular;
- Periarticular calcifications;
- Adhesive shoulder capsulitis;
- Scars with keloid evolution;
- Myofascial pain;
- Epicondylitis;
- Low back pain;
- Knee osteoarthritis;
- Shoulder periarthritis;
- Carpal tunnel syndrome;

– Varicose ulcers (healing is much faster) with 3MHz ultrasound by treating the edge of the ulcer with a commercial gel as a means of coupling (sonophoresis), or by underwater application;

CONTRA-INDICATIONS

The ultrasound treatment with ULTRASONIC-series cannot be provided in the event of:

- Tumours (Peripheral expansive proliferative stimulation);
- Osteoporosis (may worsen decalcification phenomena). While this is not an absolute contra-indication, it is advisable to use low frequency pulsed modes (16-48 Hz);
- Hematomas, risk of re-bleeding;
- Articulations with epiphysis in the bone-growing phase;
- Venous vascular affections with thrombosis or thrombophlebitis in the area to be treated in the acute phase;
- Avoid irradiating near to glands and the cardiac aia, even in healthy patients, (modification of action potentials and contractile proprieties);
- Avoid using on or close to the eyes (as the fluid means cavitation effect may lead to irreversible damage) due to a risk of hemorrhages and retinal detachment;
- Avoid carrying out treatments on abdominal or lumbar areas during menstrual cycles and during pregnancy;
- Avoid carrying out treatments in cases of cutaneous lesions and alterartions of sensitiveness (especially in diabetics with neuropathic complications);
- Patients with active implantable devices or metal prostheses.

Collateral effects

The therapeutic treatment with ultrasound has not generally contra-indications if it is made in compliance to the normal modalities.

It is pointed out that after the first-second session of treatment is possible to have an increase of the pain, that will disappear after 5-6 hours.

At maximum dosages of 2-3 W and in case of continuous emission for a duration greater than 12 minutes, it will appear a focused pain in the treatment's area and it is possible to have sick's sensation that could disappear reducing the power .

However, these phenomena are temporary.

PRELIMINARY NOTES

UNPACKING

The equipment is specially packaged for transport in a single pack complete with filling which has been specifically studied for safe transportation and storage.

To remove the equipment from the pack, place the box on a smooth, flat surface. Open the top of the box and remove the polystyrene filling. Be very careful when removing the contents of the pack.

The unit and accessories are wrapped in transparent sheets of polyethylene protection and contains the following:

- the User Manual;
- n.1 mains power supply cable;
- n.2 spare fuses (see technical specifications);
- n.1 multi-frequency probe 1/3MHz;
- n.1 Ultrasound gel bottle 260ml.

Check the contents of the package and should any of the items be missing then contact your local authorized EME srl dealer.

SETTINGS UP

The ultrasound therapy unit can be set up very quickly and easily.

The following environmental conditions are ideal when installing the equipment:

- room temperature: from +10° to +40°C;
- humidity level: from 10% to 80% without condensation;
- avoid direct exposure to sunlight, chemical products and vibrations;
- avoid using RF wireless communication devices in proximity (<0.30m)

ACCESSORIES

The device can be used with following accessories:

Description	Ultrasonic 1300	Ultrasonic 1500
Power cable supply	1	1
Spare FUSES (see technical specifications)	1	1

Description	Ultrasonic 1300	Ultrasonic 1500
User manual	**1**	**1**
TV5 ultrasound probe 1/3 MHz with a 5 cm^2 emitting surface	**1**	**2**
Ultrasound gel bottle 260ml	**1**	**1**
BO-U Orthostatic arm for all TV	x	x
American power cable supply	x	x
English power cable supply	x	x
Trolley 3 shelves (60x37x86cm)	x	x
TV1 ultrasound probe 1/3 MHz, a 1 cm^2 emitting surface	x	x
TV3 ultrasound probe 1/3 MHz, a 3 cm^2 emitting surface	x	x
TV8 ultrasound probe 1/3 MHz, a 8 cm^2 emitting surface	x	x
Smart-cards	x	x
Kit software update	x	x
Link cable for combined use of electrotherapy / ultrasound devices	x	x
Ultrasound probe with integrated water bolus kit (gel holder)	x	x
Ultrasound gel bottle 260ml	x	x
Ultrasound gel bottle 1000ml	x	x
Ultrasound gel soft pack 5000Ml	x	x
Carrying case in TNT	x	x

The ACCESSORIES that can be replaced by the RESPONSIBLE ORGANIZATION and that can influence the conformity of the EM EQUIPMENT:

Shielded cable for US handpiece connection. The cable length must be less than 3m.

The accessory installing is simple and intuitive: each cable for the therapy is equipped with a multi-pin connector to be inserted into the socket on the front panel of the device.

Contact authorized dealers EME srl for problems or difficulty installation.

CONNECTIONS

The power entry module can be found on the back of the unit and consists of a three-pole socket for the cable set, an extractible fuse box with two fuses (see technical specifications) and the main switch.

Plug the power supply cable three-pin plug into the integrated board and ensure that it is correctly plugged into the connector.

When using an extension lead, make sure that it has been earthed.

Failure to comply with the above instructions may lead to dangerous electrical discharge causing machine damage and harm to persons.

The connection of the probe/applicator is simple: you need to connect your cable to the device, inserting it into the connector.

Once you have checked that installation and assembly have been carried out according to instructions provided up to this point in the manual, switch on the machine making sure that the display screen is turned on correctly.

COMBINED USE

You can use the “LINK” cable (optional) to connect an ULTRASONIC-series unit to a THERAPIC-series unit ; this union allows to realize an hardware connection between the devices , and it allows to emit combined treatments of electro-therapy and ultrasound-therapy.

It is possible to combine the two machines simply by connecting the LINK cable to the two "LINK" connectors on the electrotherapeutic device and on the ultrasound device respectively.

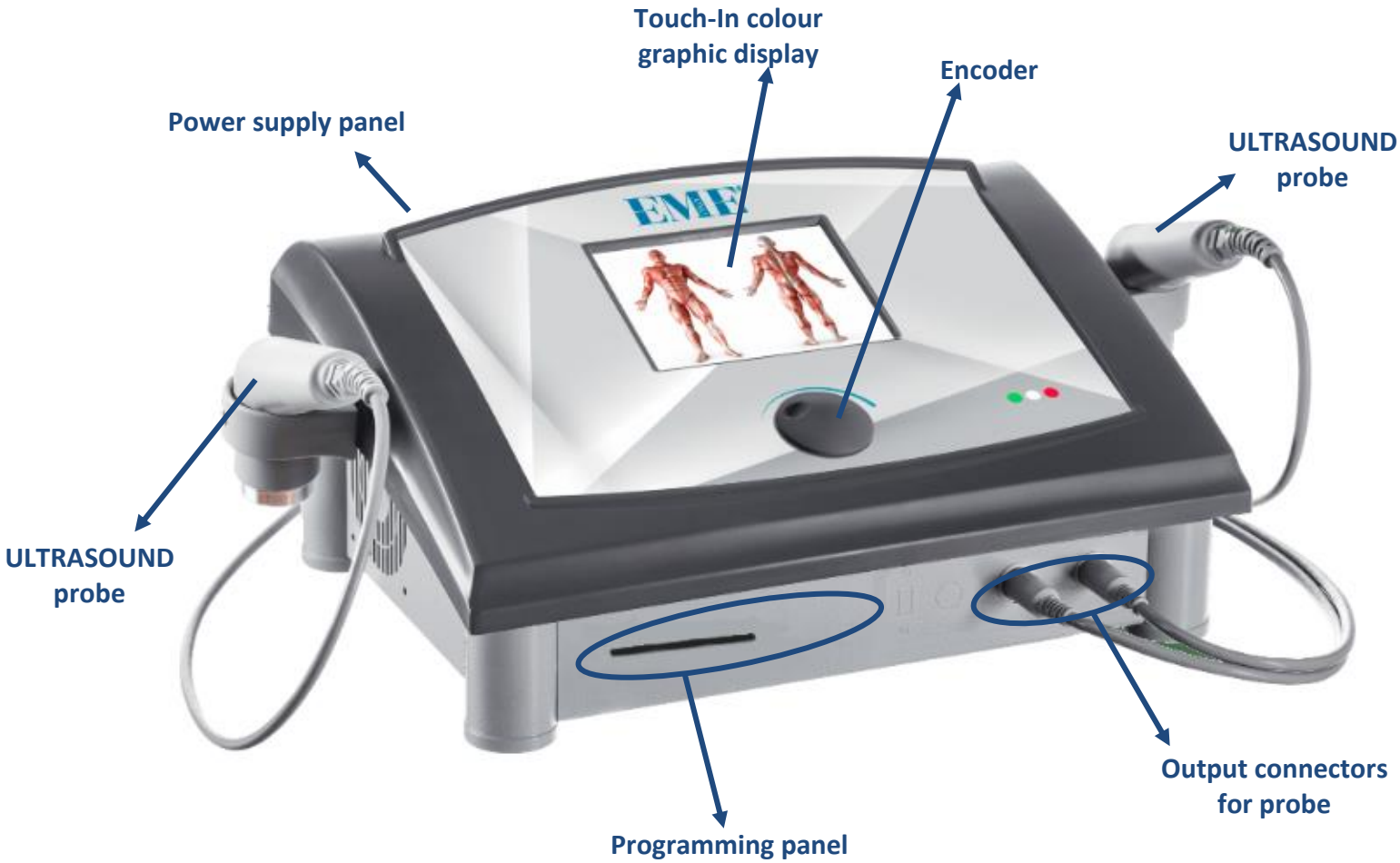
For this scope , you must to apply on the patient the positive electrode of the channel 1 of the electro-therapy and the ultrasound probe , because the ultrasound probe – due to LINK cable - represents the negative electrode of the channel 1 of the electro-therapy .This connection allows to substitute , to an hardware level , the negative electrode of the channel 1 of the electro-therapy with the ultrasound probe.

This means that :

- Pushing the START button on ULTRASONIC but not on THERAPIC, the ultrasound treatment will be emitted using the ultrasound probe.
- Pushing the START button on THERAPIC and on ULTRASONIC too , the ultrasound probe becomes the emission terminal both for the ultrasound-therapy treatment or the electro-therapy treatment.

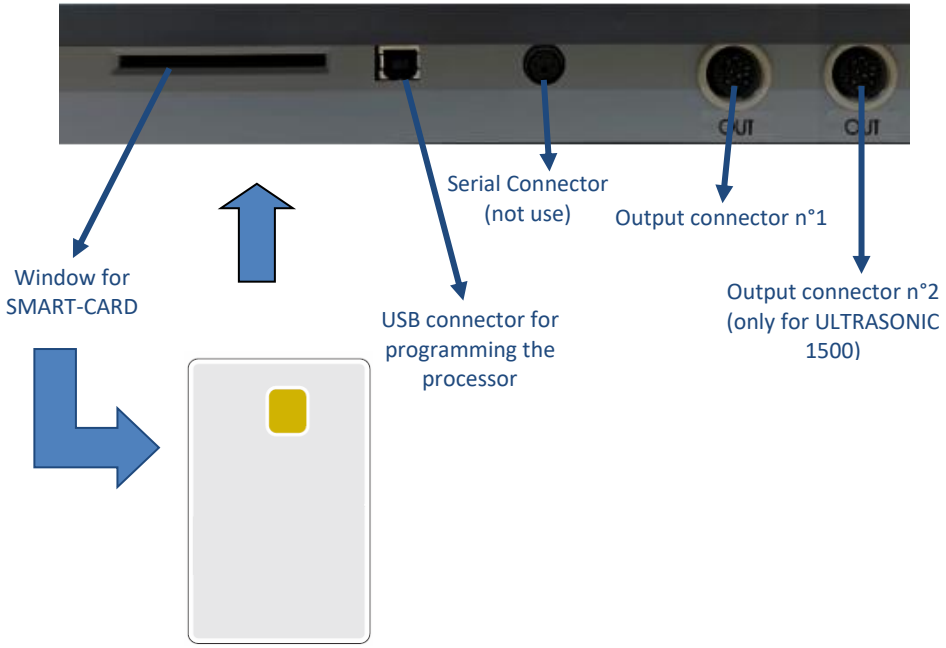
The remaining channel present in the ULTRASONIC 1500 is still available for the treatment of ultrasound therapy.

DESCRIPTION OF THE EQUIPMENT



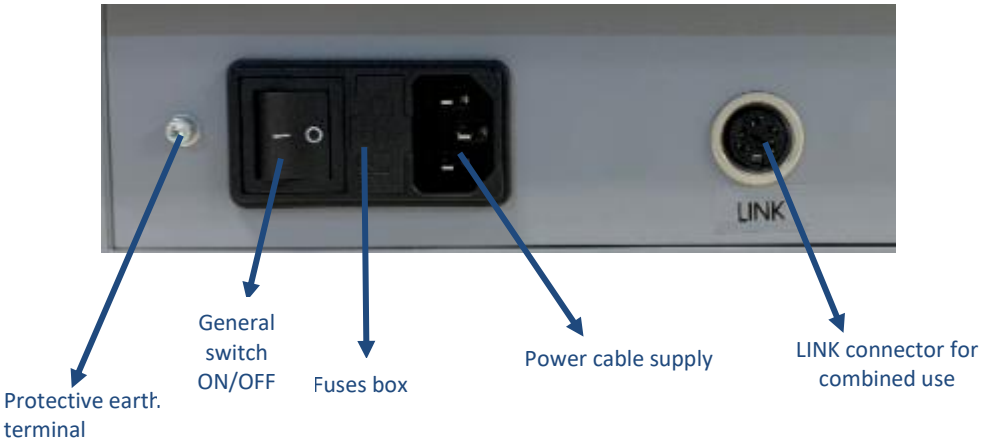
NOTE: **ULTRASONIC 1300** has only one output connector and one probe, **ULTRASONIC 1500** has two independent output channels and two probes,

PROGRAMMING PANEL



SMART-CARD

POWER SUPPLY PANEL



HOW TO USE OF THE DEVICE

This section provides important information and instructions on how to make the best use of the equipment ULTRASONIC-series.

All the control functions and the machine itself are handled and coordinated by a microprocessor: apart from making pre-memorized programs available for application, the microprocessor ensures that the machine can be personalized and operated in a highly safe and efficient manner.

Interfacing allows for the operator to communicate with the unit by means of a large, clear graphic backlit liquid crystal display screen (LCD) through which all operational messages required by the operator, work status during operation, and errors are visualized.

The following paragraphs illustrate the procedures to be carried out and the technical specifications of the ULTRASONIC-series unit . They also deal with the different options available, from the selection of a pre-memorized program for use in specific treatments as well as how to determine the correct working parameters for “personalized” applications.

BEST USE

After having installed and correctly positioned the machine as per the instructions described in the previous sections and connecting the applicator correctly, plug the machine into a 230Vac wall socket and switch on using the ON/OFF main switch on the back panel of the unit.

Once turned on, the LCD display lights up and ULTRASONIC-series unit is ready for use.

With the first turn on of the device, you can set the language from the six available. Turn the encoder to select the desired language and press it to confirm the selection. Then press the SAVE button to save the changes. A confirmation message will inform you of any modification.

After a few moments to load the settings, the LCD display will light up showing the logo (see Figure 1), and appears a screen that allows you to select between four operating modes (Fig. 2) by tapping the corresponding button on the screen.

If you want to use the Smart-Card to create new customised programmes or to run those already stored, insert it as shown in the Fig.3, with the chip facing upward.

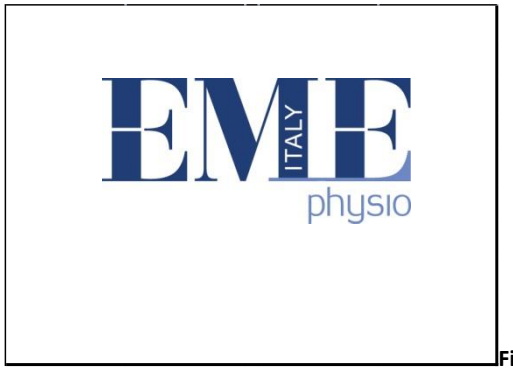


Fig.1

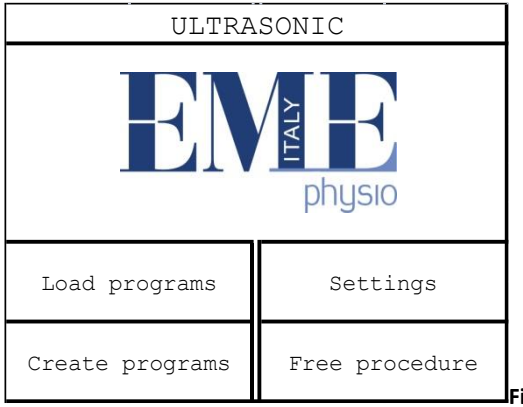


Fig.2

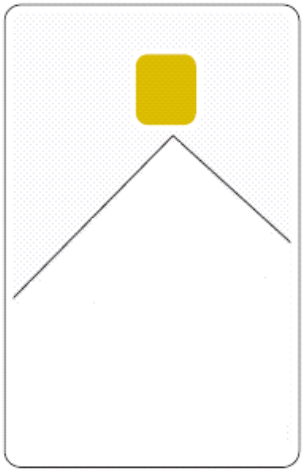


Fig.3 – SMART-CARD

SETTINGS

Allows you to edit and save to the internal memory the basic settings to be recalled automatically every time .

Pressing the button for the function SETTTINGS appears the screen of the fig.4.

Turn the encoder knob (which by default is located on the OTHER menu) select the feature you want to change, and then press the knob to confirm the selection.

On the page also appear information about the version of software and firmware of each module of the power board installed on the machine, and company contacts.

Pressing the button EXIT, to return to the screen of the fig.2.

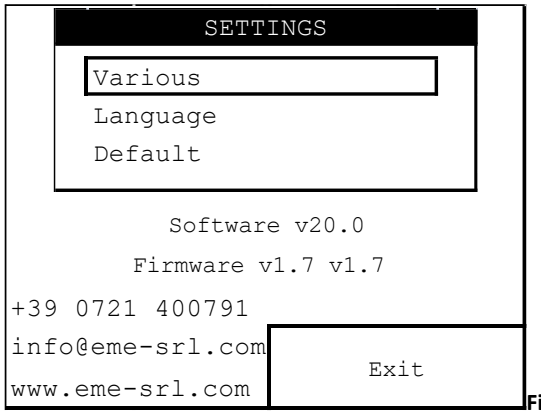


Fig.4

VARIOUS

In this section, it's possible customize or turn off the acoustic signal to suit operator preferences.

In the screen of fig.4, rotates the encoder knob to select VARIOUS section. Then press this knob to confirm the choice. Appears the screen of fig.5.

Pressing the encoder knob on the BUZZER menu, it's possible to turn on or to turn off the acoustic signal. When there is a check the horn is working.

Pressing the SAVE button, stores the desired sound settings. Instead, pressing the EXIT taste will cancel the operation. In both cases, it returns to the screen in fig.4.

In this section it's also possible to format the smart-card and the user memory.

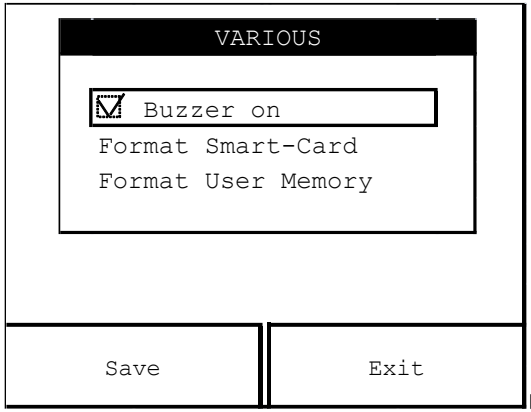


Fig.5

Formatting the smart-card is made when you insert a new card that has never been used. It can also can be used the function FORMAT SMART CARD to delete it completely, thus making it available, for example, for use on a different machine.

Select one of the memory supports to format turning to the right the encoder knob, and press this knob to confirm the choice.

In order to avoid accidental deletion, you are asked to confirm the operation (see fig.6).

Pressing the FORMAT button, the formatting operation of the selected support memory is executed. When formatting is completed, a screen will appear showing that the operation is completed (see fig.7). After a few minutes you return to the main screen of this section.

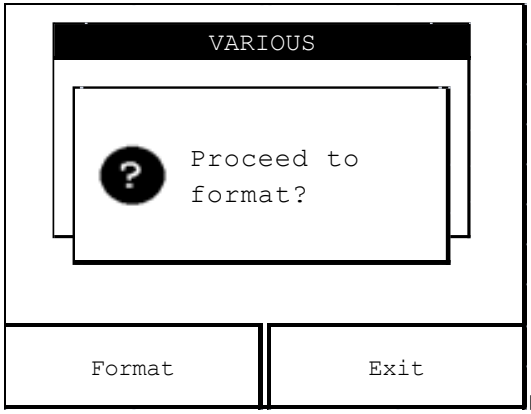


Fig.6

If you proceed with the formatting of Smart-Card but this support is not entered, the operator is informed by an error message.

Pressing the EXIT button to cancel the format operation of the selected memory support and returns to the screen in fig.5.

Pressing again the EXIT button to return to the screen in fig.4.

LANGUAGE

To choice the language in which you wish to have all the commands and messages, rotate the encoder knob then press this knob at the LANGUAGE menu (see fig.4).

For to choose the desired language, rotate the encoder knob until to reach the correspondent language, then push this knob for to confirm the choice.

Finally, press the SAVE button for to train the device to work with the selected language. Otherwise, press the EXIT button to cancel the operation. In both cases, it returns to the screen in fig.4.

Pressing the EXIT button to return to the screen in fig.2.

After a short wait for the loading of the new dictionary, you will see the menu with the new language.

To change the language back, you can repeat this procedure at any time.

DEFAULT

This section allows to set the parameters of a standard therapy that can be immediately used with the FREE PROCEDURE function

At the screen in fig.4 rotate and then press the encoder knob at the DEFAULT menu to access this section.

Fig.8 screen appears where you can configure the default program by changing parameters such as duration, handpiece frequency, effective intensity, duty cycle and duty cycle frequency. These parameters are selected by turning the encoder knob and then pressing it to highlight the selected parameter.

Then turn the knob (clockwise for increasing values or counterclockwise for decreasing values) until you reach the desired value for the parameter; then press the knob to exit the procedure.

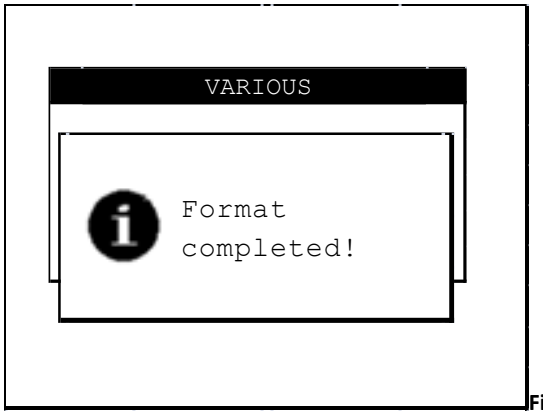


Fig.7

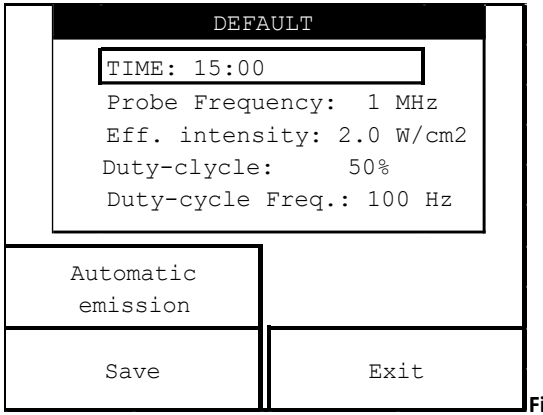


Fig.8

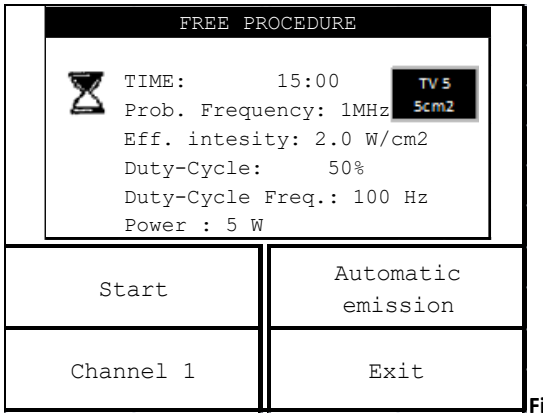


Fig.9

The percentage value that defines the DUTY CYCLE mode is the percentage of active time compared to the entire duration of the operative cycle (1/100 second). So 100% means continuous activity, while 50% means that the active stage and the following pause stage both last for the same amount of time.

Pressing the button for the function SAVE, you return to the screen of the fig 4.

Pressing the function key for the button AUTOMATIC EMISSION you can toggle between automatic emission and the continuous emission.

Pressing the EXIT button instead, we go back to the main screen of the SETUP menu (Figure 4) without having made any changes.

FREE PROCEDURE

Allows you to create customized programs that can be used immediately but not stored.

Pressing the FREE PROCEDURE taste (fig.2) appears the screen of the fig.9.

Before starting treatment you can change the treatment parameters. Select them rotating the encoder knob and then pressing it on the selected parameter. Then turn again the knob to modify the value of the parameter and push it again to exit the modification procedure of that parameter.

At the editing stage, the parameters are highlighted in black. You cannot change others or leave the function before you confirm by pressing the knob or waiting a few seconds to let the highlighting disappear.

Note: Duty-cycle (**working cycle time** or **duty cycle time**) is defined as the fraction of time that an entity goes into an active state in proportion to the total time considered.

The power varies automatically as the effective intensity and duty-cycle vary.

Pressing the CHANNEL 1 button you can select the output, to switch to channel 2. This option is available only for ULTRASONIC 1500 that has two independent output channels.

By pushing the button related to AUTOMATIC EMISSION you can choose treatment modality: between automatic emission and continuous emission. Differently from continuous modality, the automatic treatment modality starts when the probe gets in touch with the skin surface, where gel has already been applied. Moreover, if the set frequency is 3 MHz, you can only use the continuous mode while at a frequency of 1 MHz you can use both continuous and automatic.

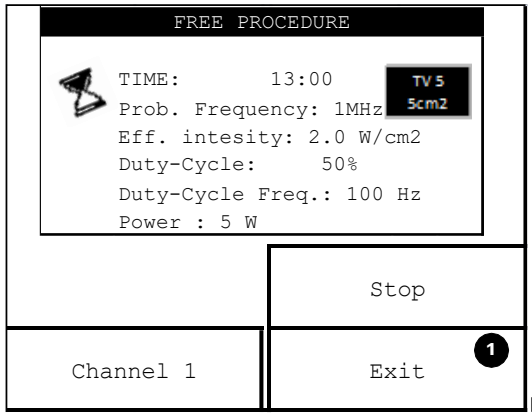


Fig.10

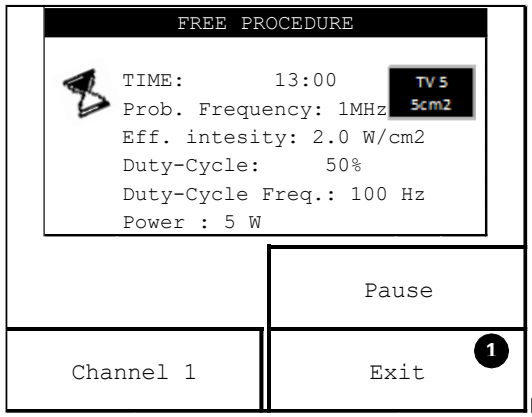


Fig.11

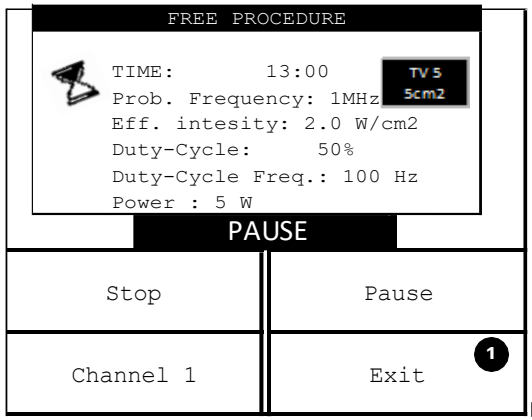


Fig.12

Press the START button to begin the selected treatment: in case of automatic emission the fig.10 screen appears; in case of continuous emission the fig.11 screen appears. In both cases a rotating hourglass shows that the device is emitting, the time parameter shows the remaining treatment time with a countdown.

During treatment delivery, the red LED on the handpiece is always on and inside the EXIT button in the display shows the output channel highlighted in black; such highlighting becomes red when the delivery of the treatment is suspended.

During treatment delivery, you can change the values of parameters of effective intensity, duty cycle and duty-cycle frequency : push the encoder knob for select the parameter and turn it to the right for increasing values or to the left for decreasing values. After a few moments the parameter is cleared.

In the case of automatic emission just remove the handpiece from the skin surface to suspend the treatment, as also shown by the red LED flashing on the handpiece, then replace the handpiece to the skin to resume the emission from the point in time when it was interrupted. Pressing the STOP button to return to the fig.9 screen.

On the other hand, in the case of continuous emission, pressing the PAUSE button pauses the emission and the red LED on the ultrasonic handpiece is off: the screen in fig.12 is then shown. By pushing again the button START the emissions resumed from the point where it was interrupted and continues until the set time runs out. Then the system communicates to the operator with a message that the treatment is finished and the software loads back the screen as in fig. 9.While pressing the STOP button the emission finally ends and you return to the screen of the fig.9.

Pressing the button for the function EXIT you return to the screen of the fig.2.

LOAD PROGRAMS

Pressing the LOAD PROGRAMS button on the screen (see fig.2), appears the list of therapeutic protocols stored in the main memory (as shown by the frame around the STANDARD PROGRAMS button which is selected by default). These programs cannot be deleted but can be overwritten by changing the parameters of interest without saving.

Instead pressing the USER PROGRAMS button, appear on the screen the numbered sections (with default parameters) that will contain the programs created with the CREATE PROGRAMS function, and you can load programs stored in the user memory.

Finally pressing the SMART-CARD PROGRAMS taste, appear on the screen the numbered sections (with default parameters) that will contain the programs created with the CREATE PROGRAMS function, and you can load customized programs, stored in the smart-card.

NOTE: If you save a program on Smart-Card but the Smart-Card is not inserted, the operator is alerted by an alarm message to the not inclusion of the Smart Card into place and then the inability to be able to continue in the operation of storage programs.

The stored programmes reflect the fruit of many years experience supporting expert professional operators. Appendix **C** shows a list of the programmes available.

Pressing the EXIT button (whatever the memory selected) returns to the screen of the fig.2.

To start the desired treatment, turn the encoder knob to reach the desired protocol, then press it to confirm the selection.

Once the display shows the selected program screen, you can go directly to its execution by simply pressing the START button.

Before initiation of therapy, however, you can modify any parameter, as discussed in FREE PROCEDURE, but the program can neither be stored nor renamed.

CREATE PROGRAMS

This function allows to store “customized” therapeutic programs in the Smart-card or in the user memory, which are the only memory available to save the new programs.

Pressing the CREATE PROGRAMS taste on the screen (see fig.2) to create a program; appears the screen of the fig.13.

Pressing the encoder knob, you can start by default the creation of the program on the user memory (as shown by the frame around the USER PROGRAM button).

Instead, press the SMART-CARD PROGRAMS button to create a program on the smart-card.

NOTE: If you save a program on Smart-Card but the Smart-Card is not inserted, the operator is alerted by an alarm message (see dfig.14) to the not inclusion of the Smart Card into place and then the inability to be able to continue in the operation of storage programs.

Once you select the support of memory in which to save the program, press the encoder knob to confirm the selection. It appears the screen of the figure 15.

At this screen, to assign a name to the program press the encoder knob: appears a cursor under the first character (see Figure.16), indicating the possibility to switch between the characters that you want to change by turning the knob. Then press the encoder knob at the character to confirm your choice.

Now the selected character is surrounded by two sliders (fig. 17), which means that the character is changed. Rotating the encoder to choose a new character to enter and press the encoder knob to confirm the selection. This exits from the routine to change the selected character.

Repeat the procedure for all the characters that you want to change, then press the OK button to confirm the new name to be entered. You return to the screen of the fig.15, where, however, the program now has a new name.

Before making the save, you can change the parameters of treatment, as described above in the FREE PROCEDURE menu.

Press the button corresponding to the SAVE button to confirm saving the custom program with the new name on the storage support initially selected. The operator will be notified of the rescue, then the screen will appear in fig.18. After a few moments it returns to the screen in fig.13.

Press the EXIT button to return to the fig.2.

MAINTENANCE

The ULTRASONIC-series device for ultrasound therapy do not require any particular maintenance operations , but only a periodic maintenance and cleanliness of the probes, in order to ensure the better operating conditions, guarantee the effectiveness of the treatment and the safety of the patient.

When cleaning the outer part of the equipment, make sure to use a soft, clean cloth dampened with luke-warm water or very mild non inflammable detergents. The front panel can be cleaned in the same way .

The probes, particularly the head of treatment, periodically should be cleaned with water and denatured alcohol. Store with care the probes at the conclusion of every treatment.

Contact authorised dealers of EME srl for information regarding original spare parts or components.

Do not spray or pour liquid onto the external parts of the equipment and onto the probes.

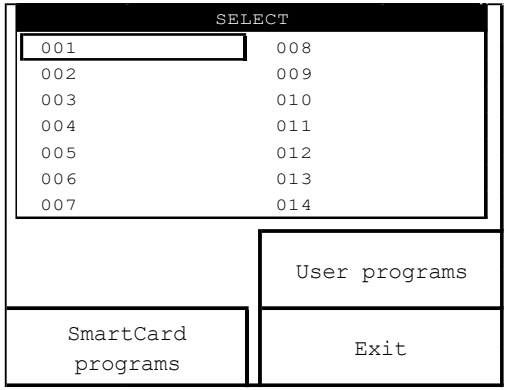


Fig.13

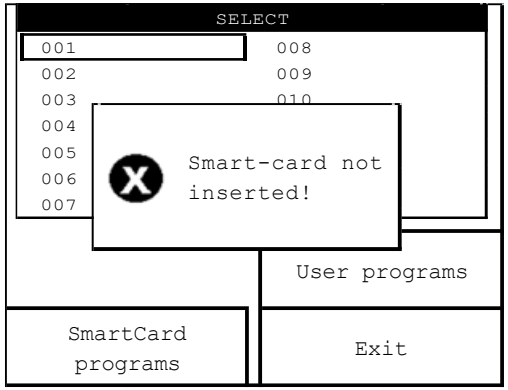


Fig.14

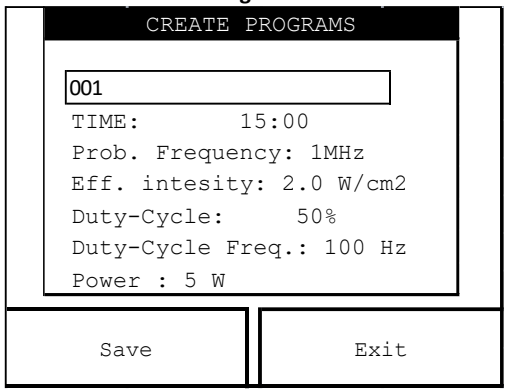


Fig.15

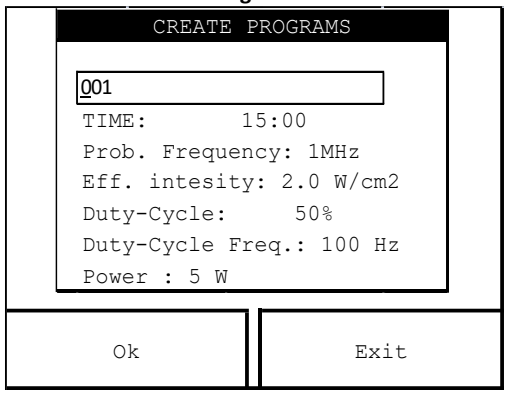


Fig.16

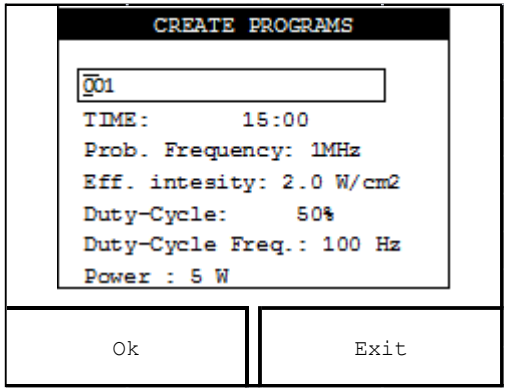


Fig.17

Fig.18

Do not immerse the unit in water.

After cleaning the external part of the equipment, make sure to dry it perfectly before turning on the unit.

The unit must under no circumstances be opened or dismantled in order to clean or check inner parts of equipment does not require cleaning of inner parts and in all cases, only specialised technicians or EME srl authorised personnel should carry out such operations.

The expected work life of device is 10 years.

TECHNICAL PROBLEMS

The equipment for ultrasound therapy ULTRASONIC-series has been designed and manufactured using highly advanced technology and first class components for reliable and efficient performance.

However, should you meet with any operational problems, we recommended that you consult the following guide before contacting any of our authorised service centres.

If any of the following situations occur, disconnect the machine and contact EME srl authorised service centres:

- the cable set or rear supply panel show signs of wear and tear or are damaged;
- the liquid has entered the equipment
- the equipment has been exposed to rain.

ELECTROMAGNETIC INTERFERENCES

The equipment for ultrasound therapy ULTRASONIC-series has been designed and manufactured according to the ELECTROMAGNETIC COMPATIBILITY DIRECTIVE 2014/30/UE with the aim of providing adequate protection from harmful interference when installed in homes and health establishments.

All required measurements and tests have been carried out in EME's internal Testing, Measurement and Inspection laboratory (LPMC), in addition to other external specialised institutes. The customer, upon prior request, may view the reports relative to EMC measures within the company.

The equipment ULTRASONIC-series does not generate significant radio frequency energy and is adequately immune to radiated electromagnetic fields. Therefore it does not detrimentally interfere with radio-electric communications, electro-medical equipment for monitoring, diagnosis, therapy and surgery, office electronic devices such as computers, printers, photocopiers, fax machines, etc. or any electric or electronic equipment used in these environments, as long as said equipment complies with the ELECTROMAGNETIC COMPATIBILITY directive .

In any case, in order to avoid any interference problems, we recommend that you operate the therapy equipment far enough away from critical equipment for monitoring vital patient functions, and that you be careful when applying therapy to patients with pacemakers.

TROUBLESHOOTING CHART

PROBLEM	POSSIBLE CAUSE	SOLUTION
Front panel LCD display or indicators don't come on: the unit doesn't work.	Mains plug not plugged in properly.	Check that the mains socket is working.
	Mains cable not properly connected to the equipment.	Plug in properly and connect cable to the equipment.
	Mains cable worn or blocked.	Replace mains cable.
	Power switch off.	Switch on the mains switch.
	Fuse or fuses defective or blown.	Substitute the missing, defective or blown fuses.
	Electronic control circuit malfunction.	Contact the EME srl assistance centre.
Some commands on the front control panel are not working properly.	Defective keys or buttons.	Contact the EME srl assistance centre.
	Electronic control system malfunction.	
This unit doesn't supply any ultrasound.	Defective connections in the patient application output circuit.	Check that the output connection is made properly.
	Handpiece probe-applicator blocked or wrongly connected.	Replace any handpiece probe-applicator that shows evident signs of wear in the supply head or cable.
	Output cable worn and/or faulty connections.	
	Current generator electronic circuit fault.	Contact the EME srl assistance centre.
The equipment works properly but there is a notable fall in treatment efficiency.	Handpiece probe-applicator output circuit not connected properly.	Carry out maintenance operations as described.
	Handpiece probe-applicator piezoelectric transducer damaged.	Check the condition of the cable and the handpiece probe/applicator connector.
	Mechanical damage (following a fall or violent impact) of the handpiece probe-applicator, especially on the radiating head.	Ensure that the radiating head adheres perfectly to the treatment surface.
	Loss of electric insulation of the piezoelectric transducer inside the handpiece probe following non authorised opening of the radiating head.	Use the acoustic conductor gel.
	Electronic circuit of the ultrasound generator not perfectly calibrated.	Contact the EME srl assistance centre.
	Possible current generator circuit fault in the equipment.	

TECHNICAL FEATURES

Main voltage:		230 Vac, 50-60Hz, ±10%
Max. Power absorption:	**ULTRASONIC 1500**	65 VA
	ULTRASONIC 1300	
Double fuse protection (T):	**ULTRASONIC 1500**	2 A - T - 5 x 20 mm for alimentation a 230Vac
	ULTRASONIC 1300	
Backlit LCD Display, to visualise and control operating parameters		Color graphic 320 x 240 pixel touch screen + encoder
Programmable treatment time		Up to 30 minutes
Class of isolation/parts applied according to the rule EN 60601-1		I / BF
Classification in compliance with the directive 93/42/CEE		II B
Protection grade from the access of liquids according to the regulation UNI EN 60601-1		IPX0
Emission frequency	**ULTRASONIC 1500**	1 MHz and 3 MHz ± 15%
	ULTRASONIC 1300	1 MHz and 3 MHz ± 15%
Duty Cycle adjustable		(10 – 100) %
Duty Cycle of frequency adjustable		(10 – 100) Hz
Continuos peak power		2 W/cm^2 ± 20%
Pulsed peak power		3 W/cm^2 ± 20%
Effective radiating area (ERA) TV1		1 cm2
Effective radiating area (ERA) TV3		3 cm2
Effective radiating area (ERA) TV5		5 cm2
Effective radiating area te (ERA) TV8		8 cm2
Output channels	**ULTRASONIC 1500**	2 independent
	ULTRASONIC 1300	1

Storable protocols in the smart-card		200
Storable protocols in the user memory		200
External dimensions of the table container (W x H x D)	**ULTRASONIC 1500**	Desktop case in plastic material (39 x H14x 30 cm)
	ULTRASONIC 1300	
Weight of the device body	**ULTRASONIC 1500**	4.25 Kg
	ULTRASONIC 1300	4.20 Kg
Conditions of use	temperature environment	(+10 ÷ +40) °C
	relative humidity	(10 ÷ 80) % without condensation
Storage/transport conditions	temperature environment	(-40 ÷ +70) °C
	relative humidity	(10 ÷ 100) % without condensation
	atmospheric pressure	(500 ÷ 1060) hPa

APPENDICES

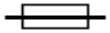
Appendix A - ENVIRONMENTAL CONSIDERATIONS

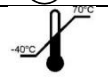
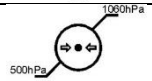
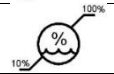
ULTRASONIC-series equipment for ultrasound therapy has been designed and manufactured to have minimal negative environmental impact, in line with its operational and safety requirements.
Rigorous standards were followed in order to minimise the amount of waste, use of toxic materials, noise, non-required radiation and energy consumption.
In accordance with careful research, the unit has been designed to optimise power consumption in keeping with energy saving principles.

This symbol means that the product should not be disposed of as domestic waste.

The user must dispose of scrap equipment by taking it to a recognised electrical and electronic recycling centre.

Appendix B – LABELS

Symbol	Signification
CE 0476	This product complies with regulations issued under the certification from a Notified Body
	Applied part BF
	Manufacturer
	Date of manufacture
	Consult instructions for use
	Attention, read the accompanying documents of the product
	The product must be dispose of as “electronic waste”, not as “domestic waste”
	Input characteristics
	Input voltage to the device
	Fuses: 2xT2AL250V
	Input power of the device (absorbed power)
	Input frequency of the device

Symbol	Signification
	Device model
	Serial number
	Output characteristics of the device
	Output power of the device
	Output frequency of the device
	Duty-cycle step
	Temperature range
	Atmospheric pressure range
	Humidity range

Symbol	Signification
LINK	Label placed near the LINK connector, used for a combined connection of unit, positioned on the rear panel of the device.
CH 1 , CH 2	Label placed near the connector for output channel 1 and channel 2 (CH2 only in the ULTRASONIC 1500).
	Label indicating devices sensitive to electrostatic charges, placed near the connector for serial connection
	Label indicating the mandatory reading of instructions, located on the front panel of the device or near the output connectors
	Labels on the probes, with their properties.

Appendix C – LIST OF THERAPEUTIC SUGGESTIONS

Reference SW	List of therapeutic treatments	Time (min)	Effective Int. (W/cm^2)	Pulsed (%)	Frequency (MHz)
PATHOLOGY 01	Algia articolaz. temporo-mandibular	8	1.5	80	1
PATHOLOGY 02	Periarticular calcifications (shoulder)	15	2.0	20	1
PATHOLOGY 03	Shoulder adhesive capsulitis	5	1.5	100	1
PATHOLOGY 04	Keloid-evolving scars	3	2.0	80	3
PATHOLOGY 05	Myofascial pain	6	1.5	100	1
PATHOLOGY 06	Epicondylitis 1	5	1.5	100	1
PATHOLOGY 07	Epicondylitis 2	10	1.0	80	1
PATHOLOGY 08	Phonophoresis	10	1.0	100	1
PATHOLOGY 09	Low back pain	6	1.0	100	1
PATHOLOGY 10	Knee osteoarthritis 1	7	2.0	100	1
PATHOLOGY 11	Knee osteoarthritis 2	5	2.5	25	1
PATHOLOGY 12	Shoulder periarthritis	7	1.5	100	1
PATHOLOGY 13	Carpal tunnel syndrome	5	1.5	100	1
PATHOLOGY 14	Varicose ulcers	2	0.3	20	3
TREATMENT 15	Localized adiposity *	10	1.0	80	3
TREATMENT 16	Orange peel skin *	10	1.0	80	3
TREATMENT 17	Facial wrinkles *	10	1.0	80	3
TREATMENT 18	Toning lower limbs (thigh)*	10	2.5	80	1
TREATMENT 19	Toning lower limbs (leg)*	10	2.0	80	1
TREATMENT 20	Toning upper limbs (forearm)*	10	1.5	80	1
TREATMENT 21	Toning muscular upper limbs *	10	2.0	80	1
TREATMENT 22	Skin tissue toning *	12	1.0	80	3

Treatment Not covered by medical CE

Appendix D – ELECTRO-MAGNETIC COMPATIBILITY TABLES

Guidance and manufacturer's declaration – electromagnetic emissions		
The ME EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the ME EQUIPMENT should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF Emissions CISPR 11	Group 1	The ME EQUIPMENT uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The ME EQUIPMENT is suitable for use in all establishments other than domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The ME EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the ME EQUIPMENT should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment –guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact	± 8kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	± 2; 4; 8; 15 kV air	± 2; 4; 8; 15 kV air	
Electrical fast transient/burst IEC 61000-4-4	± 2kV per power supply lines	± 2kV per power supply lines	Mains power quality should be that of a typical commercial or hospital environment
	± 1kV for input / output lines	± 1kV for input / output lines	
Surge IEC 61000-4-5	± 1kV line(s) to line(s)	± 1kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment
	± 2kV line(s) to earth	± 2kV line(s) to earth	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0,5 cycles	0% U_T for 0,5 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ME EQUIPMENT requires continued operation during power mains interruptions, it is recommended that the ME EQUIPMENT be powered from an uninterruptible power supply or a battery
	0% U_T for 1 cycles	0% U_T for 1 cycles	
	70% U_T for 25 cycles	70% U_T for 25 cycles	
	0% U_T for 250 cycles	0% U_T for 250 cycles	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A / m	Not applicable, the device does not contain components susceptible to magnetic fields	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE : UT is the a.c. mains voltage prior to application of the test level.			

Guide and declaration of the manufacturer - electromagnetic immunity				
The ME EQUIPMENT is designed to work in the electromagnetic environment specified below. The client or user of the ME EQUIPMENT should ensure that it is used in this environment Portable and mobile RF communications equipment should not be used closer to any part of, including cables, than the recommended separation distance calculated with the equation applicable to the transmitter frequency.				
Immunity test	Trial level of the IEC 60601		Level of compliance	**Recommended separation distance d:**
Conducted RF IEC 61000-4-6	3 Veff from 150kHz to 80 MHz		3 Veff	**d**= 30 cm
Radiated RF IEC 61000-4-3	3 V/m from 80 MHz to 2,7 GHz		3 V/m	**d**= 30 cm
Immunity to proximity fields from wireless RF communication devices IEC 61000-4-3	TETRA 400 380 – 390 MHz	27 V/m	27 V/m	**d**= 30 cm
	GMRS 460 FRS 460 430 – 170 MHz	28 V/m	28 V/m	
	LTE Band 13, 17 704 – 787 MHz	9 V/m	9 V/m	
	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 800 960 MHz	28 V/m	28 V/m	
	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 5 1700 – 1990 MHz	28 V/m	28 V/m	
	Bluetooth, WLAN, 802.11 b/g/n, RIFD 2450, LTE Band 70 2400 – 2570 MHz	28 V/m	28 V/m	
	WLAN 802.11 a/n 5100 – 5800 MHz	9 V/m	9 V/m	

DICHIARAZIONE DI CONFORMITÀ ALLA DIRETTIVA 93/42/CEE SUI DISPOSITIVI MEDICI

EME ITALY
Aesthetic & Medical Technologies

DECLARATION OF CONFORMITY TO THE 93/42/CEE DIRECTIVE ON MEDICAL DEVICES

Il Fabbricante / *The manufacturer*

EME Srl - Via degli Abeti , 88 / 1 - 61122 PESARO (PU) - ITALY

dichiara sulla sua responsabilità che il prodotto :
declares on its own responsibility that the product :

Apparecchiature per ultrasuono terapia /
Equipment for ultrasounds therapy :

ULTRASONIC 1300 - ULTRASONIC 1500

è conforme alle prescrizioni della direttiva comunitaria 93/42/CEE e successive integrazioni e modifiche (Allegato II eccetto il punto 4), recepita in Italia con D.L. N° 46 del 24 febbraio 1997 e successive integrazioni e modifiche , e la classe di rischio è la IIb secondo la regola 9.

is in compliance with the 93/42/CEE Directive and the following integrations and modifications (Annex II except point 4) , implemented in Italy following the D.L. N° 46 directive issued on 24 february 1997, and the risk class is IIb *according to the rule 9.*

Certificato n. MED – 31009 / *Certificate n. MED – 31009*

La macchina è marcata / *The equipment is marked* :

CE 0476

Organismo Notificato / *Notified Body*
Kiwa Cermet Italia S.p.a.

Pesaro, 14/04/2016

EME srl
L'Amministratore unico / Administrator

Italian manufacturer of physiotherapy equipment since 1983

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